

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA, EX REL.	:	
ANTHONY R. SPAY	:	
	:	
Plaintiffs,	:	CIVIL ACTION NO. : 09-4672
v.	:	
	:	HON. RONALD L. BUCKWALTER
CVS CAREMARK CORPORATION,	:	
CAREMARK Rx, LLC (f/k/a CAREMARK Rx,	:	
INC.),	:	
CAREMARK, LLC (f/k/a/ CAREMARK, INC.)	:	
SILVERSCRIPT, LLC (f/k/a SILVERSCRIPT,	:	
INC.),	:	
	:	
Defendants	:	

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**PLAINTIFF/RELATOR ANTHONY R. SPAY'S MEMORANDUM OF LAW IN  
SUPPORT OF HIS MOTION TO STRIKE DEFENDANTS' AFFIRMATIVE DEFENSES**

Plaintiff/Relator Anthony R. Spay ("Relator" or "Plaintiff"), by and through his undersigned counsel, pursuant to Federal Rule of Civil Procedure 12(f), respectfully submits this Memorandum of Law in Support of his Motion to Strike Defendants' First, Second, Third, Fourth, Fifth, Sixth, Seventh, Eighth, Ninth, Tenth, Eleventh, Twelfth, Fifteenth, Sixteenth, Seventeenth, Eighteenth, Twenty-Third, Twenty-Fifth, and Twenty-Eighth Affirmative Defenses.<sup>1</sup>

**I. INTRODUCTION**

In their Answer to Relator's First Amended Complaint<sup>2</sup>, Defendants CVS Caremark Corporation, Caremark Rx, LLC, Caremark, LLC, and Silverscript, LLC (collectively,

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<sup>1</sup> Relator's counsel sent Defendants' counsel a letter on February 19, 2013, explaining the deficiencies in Caremark Defendants' Affirmative Defenses, and requesting that Defendants withdraw those defenses by February 21, 2013 at 4:00 PM. Defendants' counsel did not respond to the letter. Therefore, Relator files the instant motion requesting that the Court strike Defendants' improper Affirmative Defenses.

<sup>2</sup> Defendants' Answer is attached hereto as Exhibit A.

“Defendants” or “Caremark Defendants”) raise thirty Affirmative Defenses, many of which Relator contends should be stricken for the following reasons:

- First, Caremark Defendants’ First, Second, Third, Tenth, and Eleventh Affirmative Defenses attempt to re-litigate issues which have already been decided adversely against Defendants by this Court in its ninety-eight page Memorandum and Order dated December 20, 2012;
- Second, Caremark Defendants’ Twelfth, Twenty-Third, Twenty-Fifth, and Twenty-Eighth Affirmative Defenses are not available *as a matter of law* in claims brought on behalf of the United States Government; and
- Third, Caremark Defendants’ Fourth, Fifth, Sixth, Seventh, Eighth, Ninth, Fifteenth, Sixteenth, Seventeenth, and Eighteenth Affirmative Defenses are not affirmative defenses, but mere denials of liability of the elements of Relator’s cause of action.

Motions to Strike Affirmative Defenses “save time and expense . . . by making it unnecessary to litigate defenses which will not affect the outcome of the case.” *United States v. Geppert Bros., Inc.*, 638 F. Supp. 996, 998 (E.D. Pa. 1986). Thus, by striking insufficient defenses, the Court forces the parties to focus on the essential issues and avoid litigating spurious ones. *United States v. Union Gas Co.*, 743 F. Supp. 1144, 1150 (E.D. Pa. 1990).

Relator’s discovery burden – and the related costs for all parties – will dramatically increase if Relator is forced, through interrogatories, depositions, requests for admissions, and document discovery, to unearth the factual theories, if any, upon which Caremark Defendants’ improper defenses rest. The parties have already engaged in extensive motion practice and are now poised to begin document and third party discovery.<sup>3</sup> Litigating Caremark Defendants’ improper Affirmative Defenses would require additional resources, time, and discovery, largely on issues that: (1) have already been adjudicated by this Court; (2) are legally inapplicable in this False Claims Act case; and/or (3) are not affirmative defenses at all.

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<sup>3</sup> Relator intends to begin document and third-party discovery immediately after the Rule 16 Scheduling Conference. Relator sent his draft Proposed Joint Scheduling Order to Defendants on February 8, 2013.

## II. PROCEDURAL HISTORY

On October 9, 2009, Relator filed his initial Complaint in this *qui tam* case against Caremark Defendants, asserting violations of the False Claims Act, 31 U.S.C. §§ 3729-3733 (“FCA”). (Dkt. No. 1). On August 5, 2011, Relator filed his First Amended Complaint, which included additional factual averments in support of his claims against Caremark Defendants. (Dkt. No. 15). Relator’s First Amended Complaint alleged that Caremark Defendants violated the FCA in their role as both a Pharmacy Benefit Manager (“PBM”) and Sponsor of the Medicare Part D Prescription Drug Program (“Part D Program”). The First Amended Complaint also alleged, *inter alia*, that Caremark Defendants engaged in a nationwide practice of fraudulently adjudicating and submitting improper Prescription Drug Event (“PDE”) claims to the Center for Medicaid and Medicare Services (“CMS”) under the Part D Program. Relator alleged that Defendants violated the FCA by falsely certifying that the PDE data submitted to CMS was true, accurate, and complete.

Upon consideration of the parties’ extensive briefing, the Court denied Defendants’ motion to dismiss in its entirety on December 20, 2012 finding, among other things, that: (1) the submission of PDE data is a “claim” for purposes of the FCA; (2) the certification of true and accurate data is a condition of payment for both Part D Sponsors and PBMs; (3) Relator adequately alleged violations of Sections 3729(a)(1), (a)(2), and (a)(7) of the False Claims Act; (4) Relator adequately pleaded a nationwide scheme to defraud in satisfaction of Rule 9(b); and (5) there was no public disclosure of allegations on which Relator’s allegations were based. (Dkt. No. 77)

Defendants filed their Answer containing the thirty Affirmative Defenses that are the subject of this Motion on February 1, 2013. (Dkt. No. 80).

### III. ARGUMENT

#### A. The Legal Standard for Motions to Strike Affirmative Defenses

A “court may strike from a pleading an insufficient defense or any redundant, immaterial, impertinent, or scandalous matter.” Fed. R. Civ. P. 12(f). Although generally disfavored, a motion to strike a defense for insufficiency should be granted where “the insufficiency of the defense is ‘clearly apparent.’” *Cippillone v. Liggett Group, Inc.*, 789 F.2d 181, 188 (3d Cir. 1986); *see also, Kaiser Aluminum & Chem. Sales v. Avondale Shipyards, Inc.*, 667 F.2d 1045, 1057 (5th Cir. 1982) (striking affirmative defense when insufficient as a matter of law); *Glenside West Corp. v. Exxon Co., U.S.A.*, 761 F. Supp. 1100, 1116 (D. N.J. 1991). “An affirmative defense is insufficient as a matter of law if it cannot succeed under any circumstances.” *In re Gabapentin Patent Litigation*, 648 F. Supp. 2d 641, 647-48 (D. N.J. 2009) (citation omitted). In addition, “affirmative defenses,” which are effectively no more than denials of liability of the elements of plaintiff’s cause of action, may be stricken as redundant. *See Fed. Deposit Ins. Corp. v. White*, 828 F. Supp. 304, 312-13 (D. N.J. 1993) (striking Defendants’ affirmative defense that they were not the proximate cause of the alleged harm because such argument is not an affirmative defense, but an element plaintiff must prove to establish its case).

Further, affirmative defenses are subject to the pleading requirements of the Federal Rules of Civil Procedure, and must contain something more than vague and conclusory allegations. *Dann v. Lincoln Nat’l. Corp.*, 274 F.R.D. 139, 145 (E.D. Pa. 2011); *Federal Deposit Ins. Corp. v. Modular Homes, Inc.*, 859 F.Supp. 117, 120-21 (D. N.J. 1994). There is dispute among the courts regarding whether affirmative defenses must satisfy the pleading standards established by the United States Supreme Court in *Bell Atlantic v. Twombly*, 550 U.S. 544 (U.S. 2007) and *Ashcroft v. Iqbal*, 129 S. Ct. 1937 (2009). *See Dann*, 274 F.R.D. at 147 n.6. However,

even assuming that *Twombly* and *Iqbal* do not apply to affirmative defenses, courts uniformly agree that, *at a minimum*, affirmative defenses must do more than assert “bare bones conclusory allegations,” and instead must set forth a “short and plain statement of facts and . . . allege the necessary elements of the alleged claims.” *U.S. Bank, Nat’l Ass’n v. Rosenberg*, No. 12-cv-723, 2013 WL 272061, at \*3 (E.D. Pa. Jan. 24, 2013) (quoting and citing references omitted); *Dann*, 274 F.R.D. at 145.

**B. The Caremark Defendants’ First, Second, Third, Tenth, and Eleventh Affirmative Defenses Should Be Stricken Because They Attempt to Re-Litigate Issues That Have Already Been Decided by This Court**

Five of the Affirmative Defenses listed in Caremark Defendants’ Answer are insufficient as a matter of law, because they were already presented to and rejected by this Court. Defendants improperly attempt to re-litigate issues presented in their motion to dismiss and rejected by this Court in its opinion and order dated December 20, 2012.<sup>4</sup> The defenses which were considered and rejected by this Court are as follows:

**First Affirmative Defense** – The Amended Complaint and its purported causes of action fail to state facts sufficient to adequately plead a cause of action against Defendants.

**Second Affirmative Defense** – The Amended Complaint and its purported causes of action fail to meet the pleading requirements of Federal Rules of Civil Procedure 8(a) and 9(b).

**Third Affirmative Defense** – Plaintiff’s action is barred by 31 U.S.C. § 3730(e)(4) because it is based upon the public disclosure of allegations or transactions in a criminal, civil, or administrative hearing, in a congressional, administrative, or Government [General] Accounting

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<sup>4</sup> Some of these issues were not only raised in Defendants’ motion to dismiss, but also in their response to the Government’s Statement of Interest. (Dkt. No. 73). In its twenty-page Statement of Interest, the Government rejected Defendants’ interpretation of Part D regulations and CMS guidance for purposes of the FCA. In particular, the Statement of Interest provided: (1) PDEs are “claims” for purposes of the FCA; (2) Relator adequately pleaded a violation of a condition of payment under the Part D program; and (3) PDE claims are not public disclosures under the FCA. *See* United States’ Statement of Interest at 10, 12, and 16-17. In response to the Government’s Statement of Interest, Defendants rehashed the same arguments raised in their motion to dismiss that (1) PDEs are not claims under the FCA; (2) Relator did not adequately plead a violation of a condition of payment under the Part D program; and (3) that the PDE data on which Relator complaint was “based” constituted a public disclosure for purposes of the FCA. *See* Defendants’ Response to United States’ Statement of Interest (Dkt. No. 76) at 2. This Court rejected Defendants’ twice-raised positions. *See U.S. ex rel. Spay v. CVS Caremark Corp.*, -- F.Supp.2d --, 2012 U.S. Dist. LEXIS 180602 \*61, \*116, and \*160-61 142 (E.D. Pa. Dec. 20, 2012). Defendants now seek to re-raise these issues a third time in the form of inadequately pleaded affirmative defenses.

Office report, hearing, audit, or investigation, or from the news media; and Plaintiff is not an original source as that term is defined by § 3730(e)(4)(b).

**Tenth Affirmative Defense** – Plaintiff’s claims are barred because the alleged false certifications were not a condition of payment.

**Eleventh Affirmative Defense** – Plaintiff’s claims are barred because the allegedly false implied certifications concern a statute or regulation that does not expressly require compliance as a condition of payment.

The Court should dismiss these affirmative defenses because the law of the case doctrine precludes reconsideration of issues that have already been adjudicated. *See Knit With v. Knitting Fever, Inc.*, No. 08-4221, 2009 WL 973492, at \*9 (E.D. Pa. Apr. 8, 2009) (J. Buckwalter) (striking affirmative defense where issue was previously litigated and decided on a motion to dismiss); *Modern Creative Services, Inc. v. Dell, Inc.*, No. 05-3981, 2008 WL 305747 \*4 (D. N.J. Jan. 28, 2008) (same); *Equal Employment Opportunity Comm’n. v. SSM & RC Inc.*, No. 05-6495, 2007 WL 1613580 \*2 (W.D.N.Y. June 1, 2007) (same).

**1. First And Second Affirmative Defenses**  
**(Failure to Meet Federal Pleading Requirements)**

Caremark Defendants’ First and Second Affirmative Defenses are essentially a regurgitation of the arguments raised in their motion to dismiss, specifically, that Relator’s Complaint fails to state a claim upon which relief could be granted, because the Complaint fails to meet the pleading requirements of Federal Rules of Civil Procedure 8(a) and 9(b). Mem. Supp. Mot. Dismiss at 5, 27 (arguing, *inter alia*, that Relator failed to plead the elements of a cause of action under the False Claims Act and that Relator’s “nationwide allegations fall woefully short of pleading fraud with the particularity required by Rule 9(b)”). The Court already considered Caremark Defendants’ argument, and in denying their motion to dismiss, the Court decided that Relator “sufficiently plead[ed] a cause of action under the False Claims Act” and that Relator’s nationwide FCA allegation was “pled with particularity as required by Federal

Rule of Civil Procedure 9(b).” *See U.S. ex rel. Spay v. CVS Caremark Corp.*, -- F.Supp.2d --, 2012 U.S. Dist. LEXIS 180602 at \*168-69 (E.D. Pa. Dec. 20, 2012); *see also, Equal Employment Opportunity Comm’n.*, 2007 WL 1613580, at \*2 (striking affirmative defense of failure to state a claim when Court already determined that complaint was not subject to dismissal for failure to state a claim). The Court should strike Defendants’ First and Second Affirmative Defenses because it has already ruled that Relator adequately pleaded his allegations.

## **2. Third Affirmative Defense (Public Disclosure Bar)**

The Court should strike Defendants’ Third Affirmative Defense that Relator’s claims are barred by 31 U.S.C. § 3730(e)(4) because this Court already determined as a matter of law that there was no public disclosure for purposes of the False Claims Act. *See Spay*, -- F.Supp.2d --, 2012 U.S. Dist. LEXIS 180602 at \*164. In their motion to dismiss, Defendants argued that: (1) an audit report which was part of the discovery in a 2007 case between MCS and Caremark was “publicly disclosed” and (2) that the PDE data submitted by Defendants to CMS was itself a public disclosure as a “report” available under the Freedom of Information Act. *See* Defs’ Mem. Supp. Mot. Dismiss 31-32 (Dkt. No. 45). The Court rejected both of these assertions and found that there was no public disclosure. *See Spay*, -- F.Supp.2d --, 2012 U.S. Dist. LEXIS 180602 at \*157, \*161-163. This Court stated that it “defies logic to suggest, as Defendants do, that the submission of [PDE data] could constitute a public disclosure.” *Id.* at \*162. This Court also found that because “neither of these items was publicly disclosed for purposes of the FCA”, it did not need to make any determination with regard to the “based upon” element of the public disclosure bar. *See Spay*, -- F.Supp.2d --, 2012 U.S. Dist. LEXIS 180602 at \*164.



The Court also held that because there was no public disclosure, “Plaintiff need not come forward with any proof that he falls within the exception to this bar as an ‘original source.’” *Spay*, -- F.Supp.2d -- 2012 U.S. Dist. LEXIS 180602 at \*166.<sup>5</sup> Because the Court has already determined as a matter of law that there was no public disclosure, the Court should reject Defendants’ attempt to re-litigate this issue and strike this Affirmative Defense.

### **3. Tenth Affirmative Defense (False Certifications Not A Condition of Payment)**

The Court should also strike Defendants’ Tenth Affirmative Defense because it already found that the Defendants’ alleged false certifications were a condition of payment under the Part D Program. *See Spay*, -- F.Supp.2d -- 2012 U.S. Dist. LEXIS 180602 at \*53, 61. In their motion to dismiss, Defendants argued that they could not be held liable under the False Claims Act for submission of false PDE data since the Regulation requiring the certification of the truthfulness, accuracy, and completeness of Part D data submitted to the Government only applies to Part D Sponsors and not to PBMs. *See* Def’s Mem. Supp. Mot. Dismiss 12. The Court rejected this argument, finding “that when properly interpreted, 42 C.F.R. § 505(k) makes proper certification of data a condition of payment” and that “failure of either a Part D Plan sponsor or the Sponsor’s subcontractor to submit accurate, complete, and truthful data related to payment may give rise to an FCA claim.”<sup>6</sup> *Spay*, -- F.Supp.2d --, 2012 U.S. Dist. LEXIS 180602 at \*61. Because this

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<sup>5</sup> This Court also stated that it would be “inclined to find that Plaintiff was indeed an original source” since he used his experience and skill as a pharmacist and auditor to review non-public PDE data and determine that Defendants violated numerous regulations and fraudulently billed the Part D Program. *Spay*, -- F.Supp.2d --, 2012 U.S. Dist. LEXIS 180602 at \*167 n.43.

<sup>6</sup> This Court also determined that “data related to payment includes all thirty-seven data fields on a PDE record” and that Relator adequately pleaded that Defendants falsely certified the truth, accuracy, and completeness of the PDE data fields related to payment. *See Spay*, -- F.Supp.2d --, 2012 U.S. Dist. LEXIS 180602 at \*67-68. In response to Defendants’ argument that PDEs are not claims under the FCA, the Government stated “Defendants are wrong” and that Defendants’ “unduly narrow interpretation of claim could seriously undermine the efforts of the United States to protect the integrity of the Part D Program.” United States’ Statement of Interest at 10-11 (Dkt. No. 73).



Court has already determined that Defendants' false certifications were a condition of payment under the Part D Program, the Court should strike this defense.

**4. Eleventh Affirmative Defense**  
**(False Certifications Concerning Statute Or Regulation)**

Similarly, the Court should strike Defendants' Eleventh Affirmative Defense. In their motion to dismiss, Defendants argued that because 42 C.F.R. § 505(k)(3) does not expressly condition payment upon the submission of truthful, accurate, and complete PDE data for PBMs, Relator could not plead that Defendants falsely certified compliance with any condition of payment. *See* Defs' Mem. Supp. Mot. Dismiss 12-13. The Court rejected this argument, holding that while 42 C.F.R. § 505(k)(3) does not use the "condition of payment" language found in 42 C.F.R. § 505(k)(1), a proper reading of the Regulation in context reveals that the subcontractor must similarly certify the truthfulness, accuracy, and completeness of the data as a condition of payment. *See Spay*, -- F.Supp.2d --, 2012 U.S. Dist. LEXIS 180602 at \*54.

Relator respectfully requests that the Court strike Caremark Defendants' First, Second, Third, Tenth, and Eleventh Affirmative Defenses because their applicability, or the lack thereof, to this case has already been decided by the Court.

**C. Defendants' Twelfth, Twenty-Third, Twenty-Fifth, And  
Twenty-Eighth Affirmative Defenses Should Be Stricken Because  
They Are Unavailable and/or Inapplicable as a Matter of Law**

In addition to the foregoing, at least four Affirmative Defenses raised in Defendants' Answer are insufficient as a matter of law because they are improper affirmative defenses or inapplicable against Relator / United States in this case. If permitted to stand, these defenses will unnecessarily complicate this litigation and result in the parties and the Court expending time and resources addressing issues that are inapplicable to this case.

**1. Twelfth Affirmative Defense  
(Laches, Estoppel, Waiver, Ratification,  
and/or Unclean Hands)**

The Court should strike Defendants' Twelfth Affirmative Defense because the doctrines of laches, estoppel, waiver, ratification and/or unclean hands are not applicable in this case.

First, courts have explicitly held that laches, estoppel, and unclean hands are *not* applicable against the United States in a case brought pursuant to the FCA. Because Relator stands in the shoes of the United States, the real party in interest, those doctrines are equally inapplicable against the Relator in this case. *United States ex rel. Walker v. R & F Props. of Lake County, Inc.*, 433 F.3d 1349, 1355 (11th Cir. 2005) ("relator stands in the shoes of the United States government."); *United States ex rel. Kelly v. Boeing Co.*, 9 F.3d 743, 748 (9th Cir. 1993)(same). Indeed, courts have held that these defenses are inapplicable in FCA lawsuits brought by relators on behalf of the United States. *See, e.g., United States ex rel. Head v. Kane Co.*, 668 F.Supp.2d 146, 150-51 (D.D.C. 2009) (laches); *United States ex rel. Hagood v. Sonoma County Water Agency*, 929 F.2d 1416, 142-22 (9th Cir. 1991) (estoppel) *United States, ex. rel., et. al., v. Center for Diagnostic Imaging, Inc.*, No. C05-0058-RSL, 2011 WL 6300174 at \*3 (W.D. Wash. Dec. 16, 2011) (unclean hands).

Second, with regard to waiver and ratification, only the Department of Justice, under the Attorney General of the United States, may waive or ratify FCA violations. Here, Caremark Defendants have not pled any facts that even suggest that an authorized official of the United States waived or ratified any of their fraudulent acts. *See, e.g., United States ex rel. Dye v. ATK Launch Systems, Inc.*, No. 1:06-CV-39 TS, 2008 WL 4642164, at \*3 (D. Utah Oct. 16, 2008) (finding that because Defendant did not allege that the Department of Justice waived or ratified the FCA violations at issue, "Defendant's waiver and ratification defenses fail as a matter of law and will be stricken").

**a. Laches**

Laches is inapplicable in this case. “It is well established that the United States is not subject to the defense of laches in enforcing its rights.” *United States ex rel. Freedman v. Suarez-Hoyos*, 2012 WL 4344199 \*7 (M.D. Fla. Sept. 21, 2012) (citing *United States v. Summerlin*, 310 U.S. 414, 416 (1940)); *United States ex rel. Head v. Kane Co.*, 668 F.Supp.2d 146, 150-51 (D.D.C. 2009); *United States v. St. John’s Gen. Hosp.*, 875 F.2d 1064, 1071 (3d Cir. 1989) *see also*, *United States v. Tuerk*, No. 07-2962, 2009 WL 612497, at \*1 (3d Cir. March 11, 2009) (noting that defense of laches cannot be maintained against the United States); *Modular Homes*, 859 F. Supp. at 120 (same). When the United States sues to “preserv[e] the public rights, revenues, and property from injury and loss,” it is exempt from a defense of laches. *United States v. Peoples Household Furnishings, Inc.*, 75 F.3d 252, 254 (6th Cir. 1996); *accord Dole v. Local 427, Int’l Union of Elec., Radio and Mach. Workers*, 894 F.2d 607, 610-11 (3d Cir. 1990).

Thus, where as here, Relator on behalf of the United States, brings this suit to recover losses sustained by the federal government because of Caremark Defendants’ misconduct, the defense of laches is unavailable. *See, e.g., United States ex rel. Head v. Kane Co.*, 668 F.Supp.2d at 150-51 (holding defense of laches not available against relator or United States in a False Claims Act suit); *United States ex rel. Liotine v. CDW Government, Inc.*, No. 05-33-DRH, 2012 WL 2807040 \*15 (S.D. Ill. Jul. 12, 2012) (same); *United States ex rel. Williams v. Renal Care Group*, No. 4:05-cv-985-DJS, 2008 WL 5233028 (E.D. Mo. Dec. 12, 2008) (same). Because Relator brings this suit pursuant to the FCA in order to recover public funds, the defense of laches is unavailable.

### **b. Estoppel**

It is well-settled that the United States “may not be estopped on the same terms as any other litigant.” *United States ex rel. Hagood v. Sonoma County Water Agency*, 929 F.2d 141, 142 (9th Cir. 1991) (citing *Heckler v. Comm. Health Sys. Of Crawford Cnty, Inc.*, 467 U.S. 51, 60 (1984)). Equitable estoppel does not apply against the United States in a suit to recover public funds. *Office of Pers. Mgmt. v. Richmond*, 496 U.S. 414, 434 (1990); *Monongahela Valley Hosp., Inc. v. Sullivan*, 945 F.2d 576, 588 (3d Cir. 1991). In order to prevent “fraud and corruption” the Appropriation Clause of the United States Constitution prohibits the expenditure of federal funds in violation of statute. *Richmond*, 496 U.S. at 427. For this reason, the Supreme Court has unequivocally and consistently held that “claims for estoppel cannot be entertained where public money is at stake.” *Id.* Surveying its cases, the Court noted “we have reversed every finding of estoppel that we have reviewed,” (*id.* at 422), and that “[e]ven our recent cases evince a most strict approach to estoppel claims involving public funds.” *Id.* at 426. In other words, when a defendant abuses public rights or usurps the public’s money, it may not raise equitable defenses to shield itself from attempts to redress the defendant’s wrongs. Thus, a claim of estoppel cannot lie in this FCA case, which involves recovery of public funds wrongfully obtained by Caremark Defendants.

In addition, even if estoppel were available in this case, Caremark Defendants have “otherwise failed to meet the requirements for invoking equitable estoppel.” *Monongahela Valley Hosp.*, 945 F.2d at 589. A litigant invoking estoppel against the United States “must not only prove the traditional elements of estoppel, but [they] also must prove affirmative misconduct on the part of the government.” *United States v. Asmar*, 827 F.2d 907, 912 (3d Cir. 1987); *see also Monongahela Valley Hosp.*, 945 F.2d at 589-90. Absent affirmative misconduct,

which Caremark Defendants do not allege, statements, actions, or omissions of agents and employees of the United States are insufficient as a matter of law to prevent the United States from asserting its rights.

### **c. Waiver and Ratification**

Defendants' claim that Relator's causes of action are barred by the doctrines of waiver and ratification because Relator purposely and unreasonably delayed in making known to Defendants the allegations in the Amended Complaint. The Court should strike this Affirmative Defense as it is devoid of any factual or legal support and wholly inapplicable in this case.

Only the Department of Justice, under the Attorney General, may waive False Claims Act matters or ratify False Claims Act violations. *See* 31 U.S.C. § 3730(a); *U.S. ex rel. Monahan v. Robert Wood Johnson University Hospital at Hamilton*, No. 02-5702(JAG) 2009 WL 4576097 \*7 (D. N.J. Dec. 1, 2009) ("violations of the FCA...may only be waived by the Department of Justice"); *U.S. v. Cushman & Wakefield, Inc.*, 275 F.Supp.2d 763, 771 (N.D. Tex. 2002). Here, Defendants have no facts that suggest that an authorized official of the United States ratified any of their alleged fraudulent actions, and thus they cannot invoke this purported defense. *See U.S. v. Cushman & Wakefield, Inc.*, 275 F.Supp.2d 763, 771 (N.D. Tex. 2002); *U.S. ex rel. Williams v. Renal Care Group, Inc.*, No. 4:05-CV-985-DJS, 2008 WL 5233028, \*1 (E.D. Mo. Dec. 12, 2008); *see also U.S. ex rel. Dye v. ATK Launch Systems, Inc.*, No. 1:06-CV-39 TS, 2008 WL 4642164 \*3 (D. Utah Oct. 16, 2008) (finding that because Defendant did not allege that the Department of Justice waived or ratified the FCA violations at issue, "Defendant's waiver and ratification defenses fail as a matter of law and will be stricken").

Because Defendants failed to provide any factual support that the United States waived or ratified the allegations in Relator's Amended Complaint, the Court should strike this affirmative defense.

#### **d. Unclean Hands**

Defendants baldly claim that Relator's claims are barred by the doctrine of "unclean hands." Setting aside the fact that Defendants provide no factual support for this conclusory statement, the defense fails because courts have repeatedly held that the doctrine of unclean hands is not a viable affirmative defense in a case brought under the False Claims Act. *See United States, ex. rel, et. al., v. Center for Diagnostic Imaging, Inc.*, No. C05-0058-RSL, 2011 WL 6300174 at \*3 (W.D. Wash. Dec. 16, 2011) (striking affirmative defense in FCA case brought by relator on behalf of United States and stating that a "qui tam defendant may not defend an FCA action by asserting that a qui tam plaintiff has unclean hands."); *citing Mortgages, Inc. v. U.S. Dist. Ct. for Dist. of Nev. (Las Vegas)*, 934 F.2d 209, 213 (9th Cir. 1991); *United States v. Levering*, 455 F. Supp. 1165, 1168 (D. Del. 1978) ("No unclean hands ... defense can be validly asserted against the Government ... unless it is upon the theory of respondeat superior.").

Therefore, the Court should strike this Affirmative Defense as it is devoid of any factual or legal support and wholly inapplicable in this case.

#### **2. Twenty-Third Affirmative Defense (Learned Intermediary Doctrine)**

Caremark Defendants' Twenty-Third Affirmative Defense alleges that Relator's claims are barred by the "learned intermediary doctrine." The learned intermediary doctrine provides that the manufacture or supplier of a prescription drug has no legal duty to warn a consumer of the dangerous propensities of its drug, as long as adequate warnings are provided to the prescribing physician. *See, e.g., Knipe v. SmithKline Beacham*, 583 F.Supp. 2d 602, 636 (E.D.

Pa. 2008); *Ferrara v. Berlex Labs. Inc.*, 732 F. Supp. 552, 555 (E.D. Pa. 1990). The doctrine has been applied exclusively in failure to warn and/or strict liability cases involving products such as pharmaceuticals and medical devices. *See, e.g., Mazur v. Merck & Co, Inc.*, 964 F.2d 1348, 1355-57 (3d Cir. 1992) (applying learned intermediary doctrine in case of pharmaceutical drug); *Soufflas v. Zimmer, Inc.*, 474 F.Supp.2d 737, 751 (E.D. Pa. 2007) (applying learned intermediary doctrine in case involving medical device).

The doctrine has never been applied outside of the tort context. Indeed, Relator has not uncovered a single case applying the doctrine against the United States in an FCA case. Therefore, the Court should strike Caremark Defendants' Twenty-Third Defense because it is not a defense to the alleged fraud in this case.

### **3. Twenty-Fifth Defense (Failure to Mitigate Damages)**

Caremark Defendants' Twenty-Fifth Affirmative Defense – that the United States has failed to mitigate its damages – ignores the body of case law holding that the United States has no duty to mitigate damages in cases where fraud is alleged. Courts have explicitly held that the duty to mitigate damages does not apply to fraud actions, including actions under the FCA. *See, e.g., Toppleman v. United States*, 263 F.2d 697, 700 (4th Cir. 1959), *cert. denied*, 359 U.S. 989 (1959) (“[h]aving by his fraud thrust this burden on the United States, the [defendant] cannot be exonerated by the failure of the Government to cast it off at the most propitious time.”); *United States ex. rel. Dye v. ATK Launch Sys., Inc.*, No. 1:06-CV-39, 2008 WL 4642164, at \*4 (D. Utah Oct. 16, 2008 (finding that “defense of failure to mitigate damages is an improper defense to False Claims Act claims.”). A defendant cannot interpose the conduct of the United States for its own benefit as an affirmative defense to its own misconduct. *See Federal Dep. Ins. Corp. v. Isham*, 782 F. Supp. 524, 531 (D. Colo. 1992) (striking defense of mitigation as a matter of law



when public officials act to protect industry and public generally); *see also Federal Dep. Ins. Corp. v. Oldenburg*, 38 F.3d 1119, 1121 (10th Cir. 1994), *aff'd sub nom Mandel v. Federal Deposit Ins. Corp.*, 516 U.S. 861 (1995) (holding that defense of mitigation cannot be asserted against FDIC as a matter of law); *Federal Dep. Ins. Corp. v. Healy*, 991 F. Supp. 53, 61 (D. Conn. 1998) (noting that nothing in statute imposes duty on FDIC “to minimize potential liability” of defendants).

The cases cited above involving the FDIC are instructive here. In those cases, the courts held that the FDIC had no duty, statutory or otherwise, to mitigate damages caused by the defendants’ wrongdoing because the FDIC was acting on behalf of the public interest to recover monies for the banking insurance fund. Similarly, in this case, Relator is acting in the public interest to recover monies for the United States based on Caremark Defendants’ fraudulent conduct. Accordingly, there is no duty to mitigate damages in this case.

Moreover, requiring the United States to mitigate damages in a case where fraud is committed upon the public contradicts the plain language of the FCA, which states that the United States shall recover “3 times the amount of damages which the Government sustains because of the act of that person.” 31 U.S.C. § 3729(a). As the United States has noted, the purpose of the FCA is “to compensate the Government completely for the costs, delays, and inconveniences occasioned by fraudulent claims.” *United States v. Bornstein*, 423 U.S. 303, 315 (1976); *see also, United States ex. rel. Marcus v. Hess*, 317 U.S. 537, 549, 552 (1943) (purpose of the FCA is to provide “complete indemnity” and to make the United States “completely whole”). Requiring the United States, a victim of Caremark Defendants’ fraudulent conduct, to take steps to minimize Caremark Defendant’s liability is antithetical to the purpose of the FCA.

Therefore, because the United States does not have a duty to mitigate its damages in this case, Caremark Defendants' defense concerning the United States' failure to mitigate its damages must fail.

**4. Twenty-Eighth Defense**  
**(Lack of Subject Matter Jurisdiction)**

Caremark Defendants' Twenty-Eighth Affirmative Defense avers that this Court lacks subject matter jurisdiction over this case based on the doctrines of exclusive and primary jurisdiction and failure to exhaust administrative remedies. The Court should strike this Affirmative Defense because subject matter jurisdiction is proper in this Court pursuant to 28 U.S.C. §§ 1331, 1345, as this is an action on behalf of the United States and arises under the laws of the United States of America to redress violations of the Federal FCA, 31 U.S.C. § 3729 *et seq.* Moreover, the FCA specifically provides for jurisdiction in the federal district courts of the United States for actions brought under 31 U.S.C. § 3730. *See* 31 U.S.C. § 3732.

In addition, contrary to Defendants' baseless assertion, the United States is not required to exhaust any administrative remedies before pursuing a defendant under the FCA for that defendant's submission of a materially false claim for payment. *See United States ex rel. Onnen v. Sioux Falls Independent School District No. 49-5*, 688 F.3d 410, 415 (8th Cir. 2012) (finding that no regulatory provisions preclude bringing an action under the FCA for damages caused by materially false or fraudulent claims for payment).

Therefore, Relator respectfully requests that this Court strike Caremark Defendants' Twenty-Eighth Affirmative Defense as insufficient as a matter of law.

**D. Caremark Defendants' Fourth, Fifth, Sixth, Seventh, Eighth, Ninth, Fifteenth, Sixteenth, Seventeenth And Eighteenth Affirmative Defenses Should Be Stricken As Redundant Because They Are Not Affirmative Defenses**

Caremark Defendants' Fourth, Fifth, Sixth, Seventh, Eighth, Ninth, Fifteenth, Sixteenth, Seventeenth, and Eighteenth Affirmative Defenses should be stricken as redundant because they are not affirmative defenses, but mere denials of liability of the elements of Relator's cause of action. Those Affirmative Defenses state as follows:

**Fourth Affirmative Defense** – The claims asserted in the Amended Complaint are barred, in whole or in part, because Defendants acted at all relevant times in good faith and not with any improper or illegal purpose, intent or knowledge. Each and every act or omission that Defendants are alleged to have undertaken or failed to have undertaken in the Amended Complaint was done or omitted in good faith and not with any improper or illegal purpose, intent or knowledge, and in conformity with all applicable federal and state statutes, and all applicable rules and CMS guidance promulgated thereunder.

**Fifth Affirmative Defense** – Plaintiff's claims are barred because Defendants did not act "knowingly" as that term is defined in 31 U.S.C. § 3729(b)(1).

**Sixth Affirmative Defense** – Plaintiff's claims are barred because the records or statements allegedly made, used, or caused to be made or used by Defendants were not false.

**Seventh Affirmative Defense** – Plaintiff's claims are barred because the records or statements allegedly made, used, or caused to be made or used by Defendants were not false.

**Eighth Affirmative Defense** – Plaintiff's claims are barred because there was no false claim.

**Ninth Affirmative Defense** – Plaintiff's claims are barred because Defendants made no express or implied false certification.

**Fifteenth Affirmative Defense** – Plaintiff's claims are barred because Defendants' conduct was not material to any alleged payment or receipt of money or property in connection with any alleged false or fraudulent claim.

**Sixteenth Affirmative Defense** – Plaintiff is not entitled to the damages or remedies he seeks.

**Seventeenth Affirmative Defense** – Plaintiff's claims are barred because the United States has not suffered, and it will not suffer, any damages or injury to a legally protected or cognizable interest by reason of the conduct of Defendants.

**Eighteenth Affirmative Defense** – The United States did not rely on the alleged statements, actions, or inaction of Defendants complained of in the Amended Complaint, and Defendants’ statements, actions, or inaction otherwise were not the proximate cause or cause in fact of any injury to or alleged loss by the United States.

The Third Circuit defines an affirmative defense as follows:

A matter asserted by defendant which, assuming the complaint to be true, constitutes a defense to it. A response to a plaintiff’s claim which attacks the plaintiff’s [legal] right to bring an action, as opposed to attacking the truth of [the] claim.”

*In re Sterten*, 546 F.3d 278, 284 n.9 (3d Cir. 2008) (relying on Black’s Law Dictionary 60 (6th ed. 1990) (citations and emphasis omitted).

Courts have held that alleged “affirmative defenses” that are effectively not more than denials of liability of elements of plaintiff’s cause of action may be stricken as redundant. *See Zivkovic v. S. Cal. Edison Co.*, 302 F.3d 1080, 1088 (9th Cir. 2002) (“A defense which demonstrates that plaintiff has not met its burden of proof is not an affirmative defense.”); *Solis v. Couturier*, Civ. A. No. 2:08-cv-RRB-GGH, 2009 WL 3055207, at \*4 (E.D. Cal. Sept. 17, 2009) (simple denials of elements of plaintiff’s case-in-chief that add nothing of substance to the litigation should be stricken); *Boldstar Tech., LLC v. Home Depot, Inc.*, 517 F. Supp. 2d 1283, 1291 (S.D. Fla. 2007) (“an affirmative defense which merely points out a defect or lack of evidence in the plaintiff’s case is not an affirmative defense at all.”).

Here, whether: (1) Caremark Defendants acted with the requisite intent to violate the FCA (Fourth and Fifth Defenses); (2) Caremark Defendants submitted false claims to the federal government (Sixth, Seventh, Eighth and Ninth Defenses); (3) Caremark Defendants false representations were “material” to payment of claims (Fifteenth Defense); (4) the United States is entitled to damages (Sixteenth and Seventeenth Defenses); and (5) Caremark Defendants were

the proximate cause of an alleged harm (Eighteenth Defense), are mere denials of liability – not affirmative defenses. The Court should therefore strike those defenses.

#### IV. CONCLUSION

In sum: Caremark Defendants’ (1) Second, Third, Tenth, and Eleventh Affirmative Defenses should be stricken because those issues have already been litigated and determined by this Court in its Memorandum and Order dated December 20, 2012; (2) Twelfth, Twenty-Third, Twenty-Fifth, and Twenty-Eighth Affirmative Defenses should be stricken because they are insufficient and inapplicable in this case; and (3) Fourth, Fifth, Sixth, Seventh, Eighth, Ninth, Sixteenth, Seventeenth, Fifteenth, and Eighteenth Affirmative Defenses should be stricken as redundant because they are not affirmative defenses, but mere denials of liability of elements of Relator’s cause of action. If permitted to stand, Caremark Defendants’ vague and improper affirmative defenses would force the parties to expend time and resources unnecessarily litigating issues that are not pertinent to the conduct at issue in this case.

Respectfully submitted,

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